UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,424	01/22/2004	William J. Carroll	MBHB 09-333-US	1421

20306 7590 06/17/2010

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
STOKLOSA, JOSEPH A	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
06/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,424	CARROLL ET AL.	
	Examiner	Art Unit	
	JOSEPH STOKLOSA	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,15-19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,15-19,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/10/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-5, 7-8, 15-19, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss (US 5,512,057) in view of Holsheimer et al. (US 5,643,330).

2. Reiss discloses an interferential spinal cord stimulation system with at least two pairs of electrodes (e.g. Fig. 1 and Col. 3, line 35-39), a sinusoidal pulse generator (e.g. Col. 2, line 13), stimulation frequencies greater than 500hz and less than 20Khz, and wherein the electrode pairs create a beat frequency proximate the subject's spinal cord (e.g. Col. 2, line 3-17).

3. Reiss fails to explicitly teach the use of implantable electrodes. Holsheimer teaches that it is known to use electrodes implanted to the dura matter for use in interferential spinal cord stimulation as set forth in ABSTRACT for providing the predictable results of decreasing power consumption by placing the electrode on the actual stimulation site as well as ensuring/maintaining proper placement of the electrodes in chronic stimulation patients. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Reiss with electrodes implanted to the dura matter since such a modification would provide the predictable results of decreasing power consumption by placing the

electrode on the actual stimulation site as well as ensuring/maintaining proper placement of the electrodes in chronic stimulation patients.

4. With regard to claim 2, Reiss discloses a digital to analog circuit associated with the microcontroller for generating digital signal pulses (e.g. Fig. 5B).

5. With regard to claim 3, Reiss discloses a programmable gate array integrated circuit (e.g. Col. 4, line 47-65).

6. With regard to claim 4, Reiss discloses the beat frequency is optimally only 200Hz (e.g. Col. 2, line 3-17).

7. With regard to claim 5, Reiss discloses no more than 11 volts being outputted (e.g. Col. 4, line 3-9).

8. With regard to claim 7, Reiss discloses the pulse width of the interferential signal to be no more than 500 microseconds (e.g. Col. 2, line 3-17).

9. With regard to claim 8 and 22, Reiss in view of Holsheimer disclose the invention as claimed but fail to explicitly teach the use of quadripolar electrodes. Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Reiss in view of Holsheimer with use of quadripolar electrodes since such a modification would provide the predictable results of effective and efficient stimulation as well as facilitating controlling and directing the interferential field to the target site.

Response to Amendment

10. The Declaration under 37 CFR 1.132 filed 3/10/2010 is insufficient to overcome the rejection of claims 1-5, 7-8, 15-19, and 21-22 based upon Reiss in view of Holsheimer as set forth in the last Office action because:

11. Applicant's Declaration is directed against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

12. Further Applicant's Declaration argues facts not present in the claims. Applicant states that Reiss and Holsheimer alone or in combination would be impractical for treatment of pain through stimulation of the ***Gracille nucleus and Pyramidal tract*** in the dorsal column; however Examiner considers this argument non-germane to the scope of the claims. The claims as written do not require the interferential stimulation to effect the Gracille nucleus or Pyramidal tract.

13. Further Applicant's declaration substantially changes the scope of the claimed invention. Applicant's claimed stimulation frequency range is from 500Hz-20KHz; however within the Declaration the stimulation frequency was 100 +100Hz.

Response to Arguments

14. Applicant's arguments filed 3/10/2010 have been fully considered but they are not persuasive.

15. Applicant argues Holsheimer fails to teach the electrode lead(s) are implanted. Examiner respectfully disagrees. Holsheimer discloses within the abstract, "The lead is

implanted adjacent to spinal cord dura mater with the electrodes transverse and facing the spinal cord." Examiner considers this to be a fact that Holsheimer discloses/teaches implanted electrodes and this is incontrovertible.

16. While Examiner acknowledges that Holsheimer fails to teach the explicit motivation that implantation of the electrode lead will decrease power consumption through minimizing the activation needed to perform transcutaneous stimulation, Examiner considers this to also be factual and will entertain any arguments/evidence from Applicant contrary to this. Further, a teaching-suggestion-motivation is not necessary to determine obviousness under KSR. Examiner maintains that the combination of Reiss with Holsheimer would yield predictable results. (please see MPEP 2143 Exemplary rationales).

17. Applicant argues that use of Quadripolar electrodes is not well known in the art as alleged by Examiner. Examiner cites Hess (US 6,233,488) as evidence that it is indeed well known in the art to use quadripolar electrode configurations in the spinal cord stimulation art.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

Joseph Stoklosa
Examiner
Art Unit 3762

/Joseph Stoklosa/
Examiner, Art Unit 3762 6/4/2010